

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0391
CUSTOMER NUMBER: 1737

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Medimmune Vaccines, Inc.
297 North Bernardo Ave
Mountain View, CA 94043

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Handwritten: "H" by K. Dawland 3/03/2006

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		14			14
7. Hamsters			254		254
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
FERRETS	31	1454		102	1556
WOTON RATS			25		25
					<i>Handwritten:</i> HK

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reseac teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

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DATE SIGNED

Handwritten: 4 JAN 06

Column E Explanation

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INFORMATION

1. Registration Number: 93-R-0391
2. Number of animals used in these studies: 102
3. Species (common name) of animals used in the study: Ferrets
4. Explain the procedure producing pain and/or distress.

The 102 ferrets assigned to Block E were used in [B4] research [B4] and [B4]. Infected ferrets studies may demonstrate [B4] which may be but not [B4]. The procedures involved did not cause the category E classification; rather it was the systemic [B4] from the administration of the test articles that caused discomfort to the ferrets in this category. Due to the study design there is not allowance for alleviation of these signs with analgesics or [B4] drugs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

In [B4] research studies, there is concern that the use of analgesic agents will affect the [B4] including the [B4] and would therefore affect the results and interpretation of the studies performed.

The [B4] is used as a positive control against which are measured [B4] and performance of the [B4]. The use of analgesics in these animals would invalidate this safety assessment.

In establishing [B4] ferret model to monitor the ease of transmission from an otherwise healthy animal, the ferrets are treated [B4] and the only way to reverse the side effect is to stop treatment. Stopping treatment would negate the results that we are trying to achieve.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: Food and Drug Administration (FDA) 21 CFR 610.1

Release Requirements: Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.



**MedImmune
Vaccines, Inc.**

ALL INFORMATION CONTAINED
HEREIN IS UNCLASSIFIED
DATE 11-11-2004 BY 60322

December 21, 2005

Mike Long
Inspection and Licensing Assistant
USDA, APHIS, Animal Care
Regional Office
Fort Collins, CO 80526

Dear Mr. Long:

I am responding to your request for a letter explaining why we are filing an amended Annual Report for 2005. During a recent inspection by Dr. Kim Folle, (Inspector ID: 5033) on December 5, 2005, she cited that the Annual Report should include retrospective information on animal use. Please see the attached form included with our amended report.

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MedImmune Vaccines, Inc.

JAN - 6 2006



MedImmune, Inc.

February 24, 2006

Kathleen M. Garland, VMO
Supervisory Animal Care Specialist
Western Region, Animal Care
USDA, APHIS
2150 Centre Avenue
Building B. 3W11
Ft. Collins, CO 80526

Customer Number: 1737
Registration No.: 93-R-0391

Dear Dr. Garland:

This letter is a reply to your correspondence dated February 10, 2006 which requested additional information for MedImmune Vaccine's Annual Report Amendment covering October 1, 2004 to September 30, 2005.

In the B4 ferret model, B4 is used to B4 as a means to B4. There is concern that the use of analgesic or B4 drugs to relieve possible discomfort would induce toxicity or affect B4 function of B4. Toxicity due to a single or chronic dose may be broad ranging and may involve B4 as well as B4. The development of any of these conditions would affect the development of the model and affect the interpretation of results of our assessment of susceptibility and B4 in this model B4. There is also concern that the use of drugs such as analgesics, B4 to relieve pain or distress may induce hepatotoxicity. The implications are that hepatotoxicity may affect the metabolism, bioavailability and toxicity of B4.

Literature search using keywords B4

B4

Databases evaluated: AGRICOLA, Entrez-PubMed
Dates of search: unlimited to 18Feb2006

B4

CONFIDENTIAL

B4

The test governed by the 21CFR610.1 guideline requires that we use B4 as a positive control against which the B4 phenotype and performance of the B4 is measured. The use of analgesics or B4 drugs to relieve possible discomfort would invalidate this assessment.

Should you have any questions regarding this matter, please don't hesitate to contact B6, b7c

Sincerely,
B6, b7c